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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/594,905

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Hirofumi Koda

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EXAMINER

FLOOD, MICHELE C

ART UNIT

PAPER NUMBER

1655

MAIL DATE

DELIVERY MODE

12/31/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/594,905	Applicant(s) KODA ET AL.	
	Examiner Michele Flood	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/1/2007;9/5/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgment is made to the receipt and entry of the amendment filed on September 29, 2006.

Claims 1-5 are under examination.

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

In the instant case, Applicant should avoid the use of the language, "The present invention provides a", which appears in line 1 of the abstract. Applicant may overcome the objection by replacing the phrase with A.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2-4 recite the limitation "The peripheral blood flow-improving composition" in line 1. There is a lack of clear antecedent basis for this limitation in the claims. Applicant may overcome the rejection by replacing the limitation with The composition for improving peripheral blood flow. Or, perhaps, Applicant may replace "A composition for improving peripheral blood flow" in line 1 of Claim 1 with A peripheral blood flow-improving composition to overcome the rejection.

Claim 4 recites the limitation "the mixture" in line 3. There is insufficient antecedent basis for this limitation in the claim. Applicant may overcome the rejection by adding to form a mixture, after "product" in line 3 of Claim 4.

Claim 5 recites the limitation "the peripheral blood flow-composition" in line 2. There is a lack of clear antecedent basis for this limitation in the claim.

Claim Objections

Claim 2 is objected to because of the following informalities: Claim 2, line 2 bridging line 3 recites (Lepidium meyenii Walp). Applicant may overcome the objection by italicizing the term “Lepidium meyenii” as *Lepidium meyenii* to place the claim in proper grammatical form. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-5 are rejected under 35 U.S.C. 102(a) as being anticipated by Ogawa et al. (JP 2004000171 A).

Applicant claims a composition for improving peripheral blood flow, comprising as an active ingredient, an extract of the plant of the genus *Lepidium* of the family *Cruciferae*. Applicant further claims the peripheral blood flow-improving composition according to claim 1, wherein the plant of the genus *Lepidium* of the family *Cruciferae* is maca (*Lepidium meyenii* Walp). Applicant further claims the peripheral blood flow-composition according to claim 1, containing a maca extract as an active ingredient. Applicant further claims the peripheral blood flow-composition according to claim 3, wherein the maca extract is obtained by adding an aqueous ethanol solution to a crushed maca product, and by maintaining the mixture at 40 to 85°C for extraction. Applicant claims a food and beverage product, perfume and cosmetic, or pharmaceutical product containing the peripheral blood flow-composition according to claim 1.

Ogawa teaches a composition comprising an extract of maca (*Lepidium meyenii* Walp), which is obtained by extracting ground maca in hydrous ethanol at a temperature of about 40°C for about 72 hours. The extract can be added to a food to obtain a functional food product which increases blood levels of growth hormones and stamina and is therefore considered to be effective for reducing an increase of wrinkles or gray hair and decrease in physical strength and reproductive function.

Ogawa does not expressly teach that the reference composition has the instantly claimed functional effect. However, the composition taught by Ogawa comprises the

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same ingredient disclosed by Applicant as having the functional effect for improving peripheral blood flow. Furthermore, even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.

The intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting. In the instant case, the composition taught by Ogawa comprises an aqueous ethanol extract of maca which is prepared obtained by the claim-designated process steps and experimental parameters recited in Claim 4. Therefore, the claim-designated beneficial effect is deemed inherent to the composition and food product taught by Ogawa.

“Applicant is asked to review *In re Hack*, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957). “When the claim recites using an old composition or structure and the “use” is directed to a result or property of that composition or structure, then the claim is anticipated” (MPEP 2100 pp. 2113).

The reference anticipates the claimed subject matter.

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Claims 1-3 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamada (N).

Applicant's claimed invention was set forth above.

Yamada teaches a nutrition supplement comprising a maca extract having action on nourishing, recovering from fatigue, physical strengthening, improving of liver function, invigorating, amelioration of neuralgia, amelioration of an insufficient blood circulation particularly in the cold, and hypermnesia.

The reference anticipates the claimed subject matter.

Claims 1-3 and 5 are rejected under 35 U.S.C. 102(e) as being anticipated by Zuckerman (A*).

Applicant's claimed invention was set forth above.

Zuckerman teaches a pharmaceutical composition comprising an extract of maca as an active ingredient. Zuckerman teaches that the composition allows inflow of blood to the penis. See [0010], [0014] and patent claims.

The reference anticipates the claimed subject matter.

Applicant is advised that the cited U.S. patents and patent application publications are available for download via the Office's PAIR. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources. Should you receive inquiries about the use of the Office's PAIR system, applicants may be referred to the Electronic Business Center (EBC) at <http://www.uspto.gov/ebc/index.html> or 1-866-217-9197.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michele Flood
Primary Examiner
Art Unit 1655

MCF
December 17, 2008

/Michele Flood/
Primary Examiner, Art Unit 1655